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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,660	01/20/2004	You-Lo Hsieh	18062G-005120US	3387

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,660	HSIEH ET AL	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A response of 7/20/06 to a restriction requirement of 6/19/06 elected Group I claims 1-31 with traverse.

The traverse is persuasive, and claims examined on the merits are 1-43, which are all claims in the application.

Claim Objections

Claims 1-43 are objected to because of the following informalities: Page 2 of the response to the restriction requirement lists all claims under "Amendments to the Claims". However, all 10 claims are labeled "(original)", and no claim is listed "(amended)".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

15 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20 Claims 1-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 The claims are confusing and unclear as to the location of the polymer and biological material in relation to the nanofiber and in relation to each other. The claims should require the biological material to be incorporated into the nanofibers or attached to the nanofibers as disclosed in the specification (page 11, paragraph

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0058), and the nanofiber should be required to be formed from the polymer as disclosed in the specification (paragraphs 0056, 0057 and 0064-0067).

5 In line 3 of claim 11, "polyacrylamide (PAM) as non-ionic" is unclear as how "as non-ionic" defines the polyacrylamide. Can polyacrylamide be in both ionic and non-ionic form? If this is the case, how do these forms differ?

10 In claim 20 and other claims that require a second polymer, the relationship of the second polymer to the first polymer, biological material and nanofiber is unclear. Where does the nanofiber contain the second polymer in relation to the first polymer and biological material?

15 Claim 29 is confusing by requiring polysaccharides and cellulose as both a synthetic organic polymer and a naturally occurring polymer. How can these materials be both synthetic and naturally occurring?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

20 A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

25 Claims 42 and 43 are rejected under 35 U.S.C. 102(a) as being anticipated by Jia et al (AL on 1449).

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The claims are drawn to an insoluble nanofiber comprising a polymer and a biological material.

Jia et al disclose enzyme-carrying polymeric nanofibers prepared via electrospinning. The enzyme is bound to the nanofiber as shown by scheme 1 (page 1028, left col). Various synthetic or natural polymers have been electrospun into fibers with diameters below 100 nm. Nanofibers are prepared having a diameter of 120 nm (page 1029, left col, under "Results and Discussions"). The nanofibers are prepared from polystyrene (page 1028, right col, under "Electrospinning").

The enzyme-containing nanofibers disclosed by Jia et al are inherently insoluble as claimed, and are the same as the presently claimed insoluble nanofiber. The polystyrene is a polymer and the enzyme is a biological material as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art
5 under 35 U.S.C. 103(a).

Claims 1-10, 12-18, 20-31, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jia et al in view of Wendorff et al (6,790,528 B2).

The claims require a nanofiber having a plurality of nanopores,
10 and containing a first polymer and a biological material.

Jia et al is described above.

Wendorff et al disclose producing porous nanofibers having a diameter of 20-4000 nm by electrospinning (abstract and col 2, lines 11-31, and col 3, lines 47-57). The nanofibers can be used as a
15 carrier for a catalyst, or as a biomaterial. The fibers can be prepared from a blend of polymers (col 2, lines 32-40) that can be synthetic and natural. The fibers can be subjected to surface modification (col 3, lines 36-46). The fibers can be used for making fabrics for use as a catalyst carrier (col 7, lines 29-36). The
20 fibers have a very large surface area (col 2, lines 11-13).

It would have been obvious to provide the nanofibers of Jia et al with nanopores to obtain a very large surface area as suggested by Wendorff et al producing porous nanofibers having a very large surface area for use as a catalyst carrier. The conditions of dependent
25 claims would have been obvious in view of the disclosures of the

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references. Jia et al disclose that fibers of diameter below 100 nm have been produced, and it would have been obvious to select optimum fiber diameter range as in claim 12 within the range disclosed by Wendorff et al. The diameter of nanopores in claims 13-16 would have depended on intended use of the fibers, and selecting a particular diameter for a certain use would have been obvious. The 4-nitro-phenyl chloroformate (NPC) used in scheme 1 of Jia et al is a linker as in claim 10. Wendorff et al disclose polymer blends (col 2, line 33), and a second polymer as in claim 20 would have been obvious.

Proportions of first and second polymers as in claims 21-25 would have been a matter of individual preference within the skill of the art. A fabric as in claims 38 and 39 is suggested by Wendorff et al (col 7, line 29).

Wendorff et al is a 371 of a PCT published as WO02/16680 on 2/28/02. This date is prior to the earliest date of 11/12/02 which the present application relies on for priority.

Claim Rejections - 35 USC § 103

Claims 11 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-10, 12-18, 20-31, 38 and 39 above, and further in view of Vann (6,573,089 B1).

The claims require a linker which can be polyethylene glycol (PEG) for attaching the biological material to the nanofiber.

Vann discloses using polyethylene glycol as a linker for attaching a biological molecule to a fiber (col 33, lines 61-62).

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When providing the nanofibers of Jia et al with nanopores as set forth above, it would have been obvious to use PEG as a linker to attach the biological material to the nanofibers as suggested by Vann.

Claim Rejections - 35 USC § 103

5 Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-10, 12-18, 20-31, 38 and 39 above, and further in view of Smith et al (6,821,479 B1).

The claim requires the polymer to be cross-linked.

10 Smith et al disclose forming a fiber having a diameter of 0.3 nm to 25 microns. The fiber can be cross-linked (col 16, line 7).

When providing the nanofibers of Jia et al with nanopores as set forth above, it would have been obvious to cross-link the polymer used to form the nanofibers as suggested by Smith et al.

Claim Rejections - 35 USC § 103

15 Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-10, 12-18, 20-31, 38 and 39 above, and further in view of Lockhart (6,974,673 B2).

The claim requires using PAA (polyacrylic acid) as a linker to attach the biological material to the nanofiber.

20 Lockhart discloses (col 9, line 44) using polyacrylic acid as a linker for attaching a molecular constituent to a fiber (col 2, lines 20, 31-43 and 50).

25 When providing the nanofibers of Jia et al with nanopores as set forth above, it would have been obvious to use PAA as a linker to attach the enzyme to the nanofibers as suggested by Lockhart

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disclosing using PAA as a linker to attach a molecular constituent to a fiber.

Claim Rejections - 35 USC § 103

Claims 32-35 are rejected under 35 U.S.C. 103(a) as being
5 unpatentable over the references as applied to claims 1-10, 12-18, 20-31, 38 and 39 above, and further in view of Chu et al (6,790,455 B2).

The claims require a membrane comprising the nanofiber containing a biological material and polymer.

Chu et al disclose (col 19, lines 18-20, col 22, lines 58-62, col
10 23, lines 47-50, and col 24, line 6) producing a membrane containing nanofibers for cell storage and delivery systems.

When providing the nanofibers of Jia et al with nanopores as set forth above, it would have been obvious to produce a membrane containing the nanofibers as suggested by Chu et al to obtain the
15 expected function of the membrane.

Claim Rejections - 35 USC § 103

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 32-35 above, and further in view of Vann.

20 The claim requires PEG as a linker.

Vann is described above.

When providing the nanofibers of Jia et al with nanopores and providing a membrane comprising the nanofibers as set forth above, it would have been obvious to use PEG as a linker to attach the
25 biological material to the nanofibers as suggested by Vann.

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Claim Rejections - 35 USC § 103

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 32-35 above, and further in view of Lockhart.

5 The claim requires PAA as a linker.

Lockhart is described above.

When providing the nanofibers of Jia et al with nanopores and providing a membrane comprising the nanofibers as set forth above, it would have been obvious to use PAA as a linker to attach the enzyme to
10 the nanofibers as suggested by Lockhart disclosing using PAA as a linker to attach a molecular constituent to a fiber.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff
15 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this
20 application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

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DMN
10/10/06